

# INTERNATIONAL SEARCH REPORT

International Application No  
PCT/EP2004/006426

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61K39/102 A61K39/385 A61K39/39 A61P31/04 A61K9/51

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

BIOSIS, EPO-Internal, WPI Data, PAJ

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages   | Relevant to claim No.   |
|------------|--|---|
| X          | GUPTA R K ET AL: "BIODEGRADABLE POLYMER MICROSPHERES AS VACCINE ADJUVANTS AND DELIVERY SYSTEMS" DEVELOPMENTS IN BIOLOGICAL STANDARDIZATION, KARGER, BASEL, CH, vol. 92, 1998, pages 63-78, XP001015412 ISSN: 0301-5149 | 1-4, 10, 11, 15-19, 23, 26, 27, 29, 30, 34-36, 39-41, 43, 46, 48-50, 58, 59 |
| Y          | abstract<br><br>table 1  | 1-36, 39-59   |

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

### \* Special categories of cited documents:

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

- \*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- \*Z\* document member of the same patent family

Date of the actual completion of the international search

24 November 2004

Date of mailing of the international search report

17/12/2004

Name and mailing address of the ISA

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## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages   | Relevant to claim No.   |
|------------|--|---|
| X          | BOEHM GÉRARD ET AL: "On technological and immunological benefits of multivalent single-injection microsphere vaccines."<br>PHARMACEUTICAL RESEARCH. SEP 2002,<br>vol. 19, no. 9, September 2002 (2002-09),<br>pages 1330-1336, XP002306393<br>ISSN: 0724-8741  | 1-4,10,<br>11,14,<br>16-19,<br>23,24,<br>26,27,<br>30,<br>33-36,<br>49,50,<br>58,59 |
| Y          | abstract   | 1-36,<br>39-59  |
| Y          | ---<br>RAGHUVANSHI RAJEEV S ET AL: "Improved immune response from biodegradable polymer particles entrapping tetanus toxoid by use of different immunization protocol and adjuvants."<br>INTERNATIONAL JOURNAL OF PHARMACEUTICS. 1<br>OCT 2002,<br>vol. 245, no. 1-2,<br>1 October 2002 (2002-10-01), pages<br>109-121, XP002306394<br>ISSN: 0378-5173<br>the whole document | 1-36,<br>39-59  |
| Y          | ---<br>WO 98/17310 A (DIMMINACO AG S A LTD ;<br>HILGERS LUUK (NL))<br>30 April 1998 (1998-04-30)<br>abstract<br>claims 1-28  | 1-36,<br>39-59  |
| Y          | ---<br>PEYRE MARISA ET AL: "An experimental divalent vaccine based on biodegradable microspheres induces protective immunity against tetanus and diphtheria."<br>JOURNAL OF PHARMACEUTICAL SCIENCES,<br>vol. 92, no. 5, May 2003 (2003-05), pages<br>957-966, XP002306395<br>ISSN: 0022-3549<br>abstract   | 1-36,<br>39-59  |
| Y          | ---<br>WO 02/00249 A (DESMONS PIERRE MICHEL ;<br>LEMOINE DOMINIQUE (BE); SMITHKLINE BEECHAM<br>BIO) 3 January 2002 (2002-01-03)<br>abstract<br>claims 1-29   | 1-36,<br>39-59  |
|            | ---<br>-/--  |   |

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## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages   | Relevant to claim No. |
|------------|--|-----------------------|
| A          | <p>GUPTA RAJESH K ET AL: "Evaluation of a guinea pig model to assess interference in the immunogenicity of different components of a combination vaccine comprising diphtheria, tetanus and acellular pertussis (DTaP) vaccine and Haemophilus influenzae type b capsular polysaccharide conjugate vaccine"</p> <p>BIOLOGICALS,<br/>vol. 27, no. 2, June 1999 (1999-06), pages 167-176, XP002306396<br/>ISSN: 1045-1056<br/>abstract</p> | 1-36,<br>39-59        |
| A          | <p>RICHARD A ET AL: "PRODUCTION AND MASS TRANSFER CHARACTERISTICS OF NON-NEWTONIAN BIOPOLYMERS FOR BIOMEDICAL APPLICATIONS"</p> <p>CRC CRITICAL REVIEWS IN BIOTECHNOLOGY, CRC PRESS, BOCA RATON, FL, US,<br/>vol. 22, no. 4, 2002, pages 355-374,<br/>XP009027022<br/>ISSN: 0738-8551<br/>paragraph '00B1!<br/>table 1</p>   | 1-36,<br>39-59        |
| A          | <p>NICOL F ET AL: "Poly-L-glutamate, an anionic polymer, enhances transgene expression for plasmids delivered by intramuscular injection with in vivo electroporation"</p> <p>GENE THERAPY,<br/>vol. 9, no. 20, October 2002 (2002-10),<br/>pages 1351-1358, XP002306397<br/>ISSN: 0969-7128<br/>abstract</p>  | 1-36,<br>39-59        |
| A          | <p>MILAS LUKA ET AL: "Poly(L-glutamic acid)-paclitaxel conjugate is a potent enhancer of tumor radiocurability."</p> <p>INTERNATIONAL JOURNAL OF RADIATION ONCOLOGY BIOLOGY PHYSICS,<br/>vol. 55, no. 3, 1 March 2003 (2003-03-01),<br/>pages 707-712, XP002306398<br/>ISSN: 0360-3016<br/>abstract</p>  | 1-36,<br>39-59        |

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## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages   | Relevant to claim No. |
|------------|--|-----------------------|
| A          | <p>YANG ZHIQIANG ET AL: "Poly(glutamic acid) poly(ethylene glycol) hydrogels prepared by photoinduced polymerization: Synthesis, characterization, and preliminary release studies of protein drugs"<br/>JOURNAL OF BIOMEDICAL MATERIALS RESEARCH, vol. 62, no. 1, October 2002 (2002-10), pages 14-21, XP002306399<br/>ISSN: 0021-9304<br/>abstract<br/>paragraph 'INTRODUCTION!'</p> | 1-36,<br>39-59        |
| A          | <p>DIWAN MANISH ET AL: "Enhancement of immune responses by co-delivery of a CpG oligodeoxynucleotide and tetanus toxoid in biodegradable nanospheres."<br/>JOURNAL OF CONTROLLED RELEASE, vol. 85, no. 1-3, 13 December 2002 (2002-12-13), pages 247-262, XP004397783<br/>ISSN: 0168-3659<br/>abstract</p>   | 1-36,<br>39-59        |
| A          | <p>SÁNCHEZ A ET AL: "Formulation strategies for the stabilization of tetanus toxoid in poly(lactide-co-glycolide) microspheres."<br/>INTERNATIONAL JOURNAL OF PHARMACEUTICS. 20 AUG 1999, vol. 185, no. 2, 20 August 1999 (1999-08-20), pages 255-266, XP002306400<br/>ISSN: 0378-5173<br/>abstract</p>  | 1-36,<br>39-59        |
| A          | <p>ESPARZA I ET AL: "PARAMETERS AFFECTING THE IMMUNOGENICITY OF MICROENCAPSULATED TETANUS TOXOID"<br/>VACCINE, BUTTERWORTH SCIENTIFIC. GUILDFORD, GB, vol. 10, no. 10, January 1992 (1992-01), pages 714-719, XP000537444<br/>ISSN: 0264-410X<br/>abstract<br/>page 718, left-hand column, paragraph 3<br/>-right-hand column, paragraph 1</p>   | 1-36,<br>39-59        |
| A          | <p>GLAXOSMITHKLINE NZ LTD: "Datasheet - Hiberix"<br/>NEW ZEALAND MEDICINES AND MEDICAL DEVICES SAFETY AUTHORITY, 'Online! 2002, XP002306401<br/>Retrieved from the Internet:<br/>&lt;URL:www.medsafe.govt.nz/profs/Datasheet/h/Hiberixinj.htm&gt; 'retrieved on 2004-11-18!<br/>abstract</p>   | 1-59                  |

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## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages  | Relevant to claim No. |
|------------|---|-----------------------|
| A          | <p>JIANG WENLEI ET AL: "Stabilization of a model formalinized protein antigen encapsulated in poly(lactide-co-glycolide)-based microspheres"</p> <p>JOURNAL OF PHARMACEUTICAL SCIENCES, vol. 90, no. 10, October 2001 (2001-10), pages 1558-1569, XP002306630</p> <p>ISSN: 0022-3549</p> <p>abstract</p> <p>-----</p> | 1-59                  |

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### Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:  
  
Although claim 35, 49, 50 is directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

### Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

#### Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

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| Patent document<br>cited in search report |   | Publication<br>date | Patent family<br>member(s) | Publication<br>date |
|---|---|---------------------|----------------------------|---------------------|
| WO 9817310                                | A | 30-04-1998          | AU 717349 B2               | 23-03-2000          |
|   |   |                     | AU 5313398 A               | 15-05-1998          |
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|   |   |                     | HU 0301413 A2              | 28-08-2003          |
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